



03-31-021

PTO/SB/21 (05-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	10/747,974
	Filing Date	December 30, 2003
	First Named Inventor	George M. Levinson et al.
	Art Unit	(TBA)
	Examiner Name	(TBA)
Total Number of Pages in This Submission	Attorney Docket Number	06335.00007

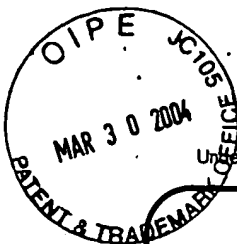
ENCLOSURES (check all that apply)					
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Preliminary Amendment <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): PTO/SB/08A form, 21 references, Exp MI #EL941344610US Return Receipt Post card			
<table border="1"><tr><td>Remarks</td><td rowspan="2">Please charge any additional fees or credit overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.</td></tr><tr><td> </td></tr></table>			Remarks	Please charge any additional fees or credit overpayment to Deposit Account No. 19-0733. A duplicate copy of this sheet is enclosed.	
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Banner & Witcoff, Ltd Robert H. Resis (Reg. No. 32,168)
Signature	
Date	March 30, 2004

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Firm or Individual name	Banner & Witcoff, Ltd Robert H. Resis (Reg. No. 32,168)
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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
(Case No. 06335.00007)

In the Application of:)
)
George M. Levinson et al.)
)
Serial No.: 10/747,974) Group Art Unit: (TBA)
)
Filed: December 30, 2003) Examiner: (TBA)
)
For: System, Method, and Computer-Readable)
Medium for Collection of Environmental Data and)
Generation of User Report for Compliance with FDA)
Requirements)

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§1.97 and 1.98, applicants wish to make the following references of record in the above-identified application. These references were cited in a Petition to Make Special filed on January 28, 2004. These references may be material to the patentability of the presently pending claims. A copy of the reference cited below are enclosed along with a completed PTO/SB/08A form.

U.S. Patents

	<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
1.	4,298,955	Munday et al.	11-03-81
2.	5,103,391	Barrett	04-07-92
3.	5,631,839	Lemoine	05-20-97

U.S. Patents

	<u>Patent No.</u>	<u>Inventor</u>	<u>Issue Date</u>
4.	5,691,895	Kurtzberg et al.	11-25-97
5.	5,719,796	Chen	02-17-98
6.	5,787,021	Samaha	07-28-98
7.	5,798,945	Benda .	08-25-98
8.	5,838,906	Doyle et al.	11-17-98
9.	5,862,054	Li	01-19-99
10.	5,892,690	Boatman et al.	04-06-99
11.	6,163,732	Petke et al.	12-19-00
12.	6,437,692	Petite et al	08-20-02
13.	6,523,045	Beatty	02-18-03
14.	6,539,271	Lech et al.	03-25-03
15.	6,574,522	Douglas	06-03-03
16.	6,604,023	Brown et al.	08-05-03

Other Prior Art – Non-Patent Literature Documents

17. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (3 sheets);
18. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (2 sheets);
19. BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (3 sheets);
20. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS), in connection with 21 CFR Part 11 Compliance Assessment (4 sheets);

21. Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (168 sheets).

The present Disclosure Statement is being submitted in compliance with 37 C.F.R. 1.56 as an Examiner might consider the cited documents important in deciding whether to allow the application to issue as a patent, but the citation of such documents is not to be construed as an admission that such documents are necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner in the normal course of examination, will make an independent search and will determine the best prior art and in the course of such search, will review for relevance the documents cited on the attached form even if not initialed.

The accompanying Information Disclosure Statement is being filed within three months of the U.S. filing date or before the mailing date of a first Office Action on the merits. No certification or fee is required.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Dated: March 30, 2004

By:



Robert H. Resis

Reg. No. 32,168



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet

2

of

2

Complete if Known

Application Number

Filing Date

First Named Inventor

Group Art Unit

Examiner Name

Attorney Docket Number

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Compliance Software Solutions Corp. web page description of its Environmental Monitoring Software System (EMSS) (3 sheets);	
		BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (2 sheets);	
		BD Diagnostic Systems, Industrial web page description of the Environmental Monitoring Software System (EMSS) of Compliance Software Solutions Corp. (3 sheets);	
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Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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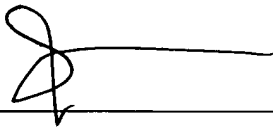


**CERTIFICATE OF MAILING
(PATENT)**

Express Mail No. EL941344610US

Deposited March 30, 2004

I hereby certify that the attached correspondence, identified below, is being deposited with the United States Postal Service as "Express Mail Post Office to Addressee" under 37 CFR 1.10 on the date indicated above and is addressed to the Attn: Commissioner for Patent, P.O. Box 1450, Alexandria, VA 22313-1450.

By: 

Application of: George M. Levinson

Title: System, Method, and Computer-Readable Medium for Collection of Environmental Data and Generation of User Report for Compliance with FDA Requirements

Serial No. 10/747,974

☒ Transmittal sheet (in duplicate)

☒ Information Disclosure Statement

☒ 21 references

☒ PTO/SB/08A form

☒ Return Receipt Postcard

Attorney Docket No. 06335.00007

BANNER & WITCOFF, LTD.

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